UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION **MDL No. 2326**

THIS DOCUMENT RELATES TO THE FOLLOWING CASES:

ALL WAVE THREE CASES

RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF DR. STEPHEN SPIEGELBERG, PH.D.

Defendant Boston Scientific Corporation ("Boston Scientific") submits the following Response in Opposition to Plaintiffs' Motion and Memorandum of Law in Support of Their Motion to Exclude the Opinions and Testimony of Stephen Spiegelberg, Ph.D. ("Mtn. to Exclude Dr. Spiegelberg").[1] Boston Scientific respectfully shows the Court as follows:

INTRODUCTION

Plaintiffs' Motion to Exclude Dr. Spiegelberg largely outlines points for cross-examination while misstating the record and providing no support for their arguments. Dr. Spiegelberg is a highly-qualified chemical engineer and polymer expert. He is the president and co-founder of Cambridge Polymer Group, Inc., where he directs a team of scientists and engineers who perform contract research, analytical testing, and device development for the biomedical and polymer communities. He has a Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology. He was a post-doctoral fellow at Harvard University and at the Massachusetts Institute of Technology. He has published numerous research articles in various fields, including

[1] A true and accurate copy of Dr. Spiegelberg's expert report is attached as Exhibit A.

polymer chemistry, medical devices, laboratory standards and the properties of polymeric materials. Dr. Spiegelberg and his company, Cambridge Polymer Group, are highly-regarded within their field. Dr. Spiegelberg has almost thirty patents and currently seven different medical device companies market his inventions.

This Court has previously ruled on the arguments in Plaintiffs' Motion and the same rulings should apply here, as Dr. Spiegelberg offered the same opinions and Plaintiffs' do not identify any additional bases for excluding his opinions. *Frankum v. Boston Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at *36 (S.D.W. Va. May 1, 2015).

In support of their Motion to Exclude Dr. Spiegelberg, Plaintiffs assert the following arguments: (1) Dr. Spiegelberg should not be allowed to offer testimony regarding position statements of medical organizations; (2) Dr. Spiegelberg should be precluded from offering "state of mind, intent and 'scientific validity'" opinions regarding the Chevron Phillips' Medical Application Caution contained within the Marlex HGX-030-01 Material Safety Data Sheet ("MSDS"); (3) Dr. Spiegelberg is not qualified to offer opinions relating to the FDA 510(k) Clearance Process or Boston Scientific's compliance with that process; (4) Dr. Spiegelberg's opinions regarding "black specks" are unreliable; (5) Dr. Spiegelberg's testing of explanted meshes should be excluded because it lacks a reliable methodology; and (6) Dr. Spiegelberg's general causation opinions should be limited due to the limitations of certain testing methods. These arguments fail for several reasons.

First, Dr. Spiegelberg is not offering opinions regarding position statements of medical organizations.[2] Second, Dr. Spiegelberg will not opine regarding the state of mind or intent of Chevron Phillips. But the scientific validity of a statement regarding the use of polypropylene in

the human body is within his domain and permissible expert testimony. Additionally, Dr. Spiegelberg has extensive experience with the testing and standards related to the design of medical devices and is qualified to offer opinions on this topic. His opinions regarding the design and development of the Boston Scientific mesh products are independent of any FDA regulation or process.

Further, Dr. Spiegelberg's testing – both for black specks and oxidation – have reliable bases. His black speck testing was based on his microscopic examination of the mesh. His testing of explanted mesh from individual plaintiffs utilized an established protocol and industry-standard analytical techniques. This testing offers relevant and reliable information regarding the explant samples tested. Finally, Dr. Spiegelberg's general causation opinions in no way should be limited as they are based on a wide range of data, literature, and his professional experience in the field of biomaterials, medical plastics, and medical devices.

Boston Scientific respectfully requests that this Court deny Plaintiffs' Motion to Exclude Dr. Spiegelberg's Opinions and Testimony. The opinions Dr. Spiegelberg offers in these cases are within his knowledge, skill, experience, training, and education; are based on sufficient facts and data; are derived from reliable scientific principles and methods; and will be helpful to the jury. Fed. R. Evid. 702.

ARGUMENT

A. Dr. Spiegelberg Offers No Opinions Regarding Position Statements of Medical Organizations.

As noted in Plaintiffs' Motion, Dr. Spiegelberg's report does not disclose any "opinions" regarding position statements of medical organizations. Nor are any position statements of medical organizations addressed during his most recent deposition. *See generally* January 14,

2015 Deposition of Dr. Stephen Spiegelberg ("2015 Spiegelberg Dep.").[3] To the extent Dr. Spiegelberg relies on a position statement in support of his opinions, that reliance is appropriate under Federal Rule of Evidence 703. Federal Rule of Evidence 703 allows an expert witness to "base an opinion on facts or data in the case that the expert has been made aware of or personally observed." This includes inadmissible evidence—including hearsay—"[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703; *see also United States v. Leeson*, 453 F.3d 631, 637 (4th Cir.2006) (holding that a district court did not abuse its discretion by admitting expert testimony based on hearsay when it had been "sufficiently established" that such hearsay statements were the type of information "reasonably relied upon by experts in [the] field"). Plaintiffs' Motion does not challenge Dr. Spiegelberg's opinions as expressed in his expert reports, but rather makes a blanket attack on the position statements of pertinent medical organizations, and should be denied.

B. Dr. Spiegelberg Offers No Opinions on Chevron Phillips' State of Mind or Intent Related to the MSDS.

Contrary to Plaintiffs' Motion, Dr. Spiegelberg is not offering opinions regarding Chevron Phillips' state of mind or intent regarding the Medical Application Caution. As this Court previously addressed this issue, Dr. Spiegelberg revised his expert report to provide assurance that he is not seeking to opine regarding state of mind or intent. This Court has limited Dr. Spiegelberg's testimony on the MSDS only as it relates to "Chevron Phillips' state of mind or intent associated with the MSDS . . . ." *Tyree v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *105 (S.D. W. Va. Oct. 17, 2014) (Goodwin, J.). Plaintiffs' attempt to exclude "scientific validity" opinions is misguided. A core purpose of expert testimony is to provide

[3] A true and correct copy of excerpts from the January 14, 2015 deposition of Dr. Stephen H. Spiegelberg is attached as Exhibit B.

scientific and technical knowledge, including addressing the scientific validity of certain principles and theories, to assist the jury. Fed. R. Evid. 702 ("A witness who is qualified as an expert…may testify in the form of an opinion or otherwise if…the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"). It is wholly within the realm of expert testimony in these cases to address whether there is scientific evidence that polypropylene should or should not be permanently implanted in the human body. Indeed, it is the center of Plaintiffs' case. If there is scientifically valid information that supports the substance of the Medical Application Caution, Plaintiffs are free to cross-examine Dr. Spiegelberg with that information at trial.

C. Dr. Spiegelberg is Qualified to Testify Regarding the Industry Standards for the Design and Development of Medical Devices.

Plaintiffs' next argument purports to address opinions of Dr. Spiegelberg about the FDA 510(k) process. This Court's position regarding FDA evidence is clear. Boston Scientific and Dr. Spiegelberg will not run afoul of this Court's rulings. The testing and standards explained in Dr. Spiegelberg's expert report can readily be addressed independent of the FDA 510(k) process. For example, Dr. Spiegelberg explains in his report that ISO 10993 standards "are the industry standard battery of tests for establishing biocompatibility of medical devices." Report at p. 16. To reach his opinions regarding Boston Scientific's design process, Dr. Spiegelberg relied upon recognized and accepted standards in the medical device industry, including ISO standards and ASTM standards. Indeed, Dr. Spiegelberg himself has served on ASTM task forces to develop these industry standards. His opinions are also based on his review of the Design History Files for the Boston Scientific devices, containing a multitude of testing and laboratory analysis, descriptions of Boston Scientific's product design process, and other technical information. As this Court previously recognized when addressing the same arguments made by Plaintiffs, "to the extent Dr.

Spiegelberg intends to opine on ISO standards without referencing the FDA, I find him qualified to do so." *Frankum v. Boston Sci. Corp.*, No. 2:12-CV-00904, 2015 WL 1976952, at *36 (S.D.W. Va. May 1, 2015).

As to Dr. Spiegelberg's qualifications, he has spent decades analyzing, characterizing, and developing biomaterials and medical devices. *See* Curriculum Vitae of Dr. Stephen Spiegelberg, Report at Exhibit 1. He has consulted with numerous medical device companies and gained specialized knowledge regarding the medical device design and development process. He has at least twenty-eight patents from his work in the medical device field. *Id.* Seven different medical device companies currently market his inventions. *Id.* Dr. Spiegelberg has extensive experience in the field of medical device analysis and design and his opinions regarding industry standards for testing are independent of the FDA 510(k) process. For these reasons, Plaintiffs' Motion should be denied.

D. Dr. Spiegelberg's Opinions Regarding Black Specks are Reliable.

Plaintiffs' discussion of Dr. Spiegelberg's opinion on black specks is wrought with misstatements of his testimony and the reproducibility of his data. As this Court stated, "[c]hallenges to Dr. Spiegelberg's ultimate conclusion with regard to the nature of the black specks are better suited for cross-examination." *Frankum*, 2015 WL 1976952, at *37. Plaintiff's motion (based on the same arguments) should be denied for the reasons restated below.

To begin, while reviewing Dr. Dunn's report and data, Dr. Spiegelberg was intrigued by Dr. Dunn's opinion that there were "black specks" in the polypropylene monofilaments because he had not observed the same. Dr. Spiegelberg examined a piece of Polyform mesh under the microscope, as was done by Dr. Dunn, and observed that any "black specks" or "black spots" present moved as he re-oriented the mesh. 2015 Spiegelberg Dep. at 18:7-14; 19:13-20:5. He

observed that this was due to reflections of light in the curvature of the mesh. Report at p. 12. While Plaintiffs contend that Dr. Spiegelberg "did not even bother to review the photos supplied by Dr. Dunn," both Dr. Spiegelberg's reliance materials list and his deposition testimony confirm that he did review Dr. Dunn's report and data. *See* Expert Report at Exhibit 2, p. 1 and 2015 Spiegelberg Dep. at 16:9-17:1; 27:2-14. Plaintiffs also contend that Dr. Spiegelberg's observations are not reproducible, but, in fact, Dr. Spiegelberg still has the piece of Polyform mesh that the monofilament was unraveled from and could reproduce the testing in short order. 2015 Spiegelberg Dep. at 22:3-8; 23:8-11. Moreover, if Plaintiffs have contradictory evidence, cross-examination is the proper method to challenge Dr. Spiegelberg's conclusions regarding the presence of "black specks" in the polypropylene monofilaments. Indeed, Plaintiffs' only source of contradiction stated in their Motion is their own expert's conclusion based on microscopic observation and photographs, not any testing of the black specks. Because Dr. Spiegelberg's conclusions regarding "black specks" were reached using a reliable method, Plaintiffs' Motion should be denied.

E. Dr. Spiegelberg's Explant Testing Utilized a Reliable Methodology and is Relevant to the Case.

Plaintiffs' argument regarding Dr. Spiegelberg's testing of various explanted meshes is a litany of attacks without citing any scientific support, either in their Motion or during Dr. Spiegelberg's deposition. Indeed, Plaintiffs spend over four pages raising their perceived issues with Dr. Spiegelberg's testing but fail to cite a single scientific article to support their contentions. Further, Plaintiffs misrepresent and ignore Dr. Spiegelberg's testimony regarding the bases of his testing. But foremost, Plaintiffs criticisms of Dr. Spiegelberg's testing are more appropriate for cross-examination. The Court recognized that challenges to Dr. Spiegelberg's opinions based on

FTIR and EDS testing of mesh samples should be raised in cross-examination at trial. *See Frankum*, 2015 WL 1976952, at *37.

In regard to its "gatekeeper" role, this Court has stated that it "'need not determine that the proffered expert testimony is irrefutable or certainly correct' . . . [a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Tyree v. Boston Scientific Corp.*, 2014 WL 5320566, at *3 (citing *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998) (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful")).

Dr. Spiegelberg has completed testing of various explanted mesh samples. Dr. Spiegelberg's testing protocol for each sample consisted of a series of steps to remove biologic tissue and materials from the explanted samples. Supp. Report at p. 1.[4] Dr. Spiegelberg then conducted Fourier Transform Infrared Spectroscopy (FTIR) and Scanning Electron Microscopy (SUM) on all samples. *Id.* He conducted Electron Dispersive Spectroscopy (EDS) on those samples where cracking was observed on SEM. Supp. Report at p. 1; 2015 Spiegelberg Dep. at 67:13-19. The reason he conducted EDS on areas where cracking was observed was to "ascertain…what was cracking off the surface, was it polypropylene, was it the biological material." 2015 Spiegelberg Dep. at 68:20-69:3.

1. Dr. Spiegelberg's Testing Protocol was in Accordance with ASTM Standards and Standard Laboratory Practices.

While Plaintiffs characterize Dr. Spiegelberg's protocol as "self-created," all of its steps are part of standard laboratory practices, are utilized in ASTM standards, and/or are reported in the peer-reviewed, published literature. 2015 Spiegelberg Dep. at 69:14-21. Plaintiffs primarily

[4] *See, e.g.,* Testing Report attached as Exhibit C.

take issue with two steps of the cleaning process – the use of a potassium hydroxide soak and the use of a hexane soak. Both of these steps are utilized in ASTM standards for the cleaning of explanted medical devices. The potassium hydroxide soak is utilized in ASTM F561 - Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids. 2015 Spiegelberg Dep. at 37:21-38:12. The hexane soak is described in ASTM F2102 – Standard Guide for Evaluating the Extent of Oxidation in Polyethylene Fabricated Forms Intended for Surgical Implants. *Id.* Plaintiffs argue that the potassium hydroxide soak could have resulted in "the destruction of Plaintiffs' evidence." Mtn. to Exclude at p. 7. The purpose of the potassium hydroxide soak is to remove biologic tissue adhered to the explant. 2015 Spiegelberg Dep. at 38:14-21. During his deposition, Dr. Spiegelberg testified regarding whether potassium hydroxide would react with the amide groups (e.g. proteins) or the additives in the polypropylene mesh. 2015 Spiegelberg Dep. at 127:10-128:3. Dr. Spiegelberg further testified that "[p]otassium hydroxide isn't going to chemically modify the polypropylene, the antioxidants, or the proteins, other than dissolving ligand between the proteins so that the material can fall apart." *Id.* at 131:4-18. There is no chemical modification because "[y]ou'd have to modify the chemical nature of the polypropylene for that to happen, and potassium hydroxide won't." *Id.* at 131:19-132:1. If Plaintiffs disagree with Dr. Spiegelberg's analysis of the chemical relationship between polypropylene, proteins, and potassium hydroxide, it is a proper area for cross-examination, not a basis to exclude Dr. Spiegelberg's testing. To the extent Plaintiffs are purporting that free radicals are created during the break down of the tissue/protein and that these free radicals are causing "destruction" of oxidized surface polypropylene, they have cited no scientific literature to provide a basis for this concern. Instead, they make unsupported attacks on Dr. Spiegelberg, whose career has focused on the analysis of medical plastics, including the oxidation of plastics, since the 1980s.

Moreover, they ignore that the potassium hydroxide soak is *recommended* by the ASTM standards for explanted device cleaning.

Plaintiffs continue their criticism by taking issue with the hexane soak utilized by Dr. Spiegelberg, which is described in the industry-accepted ASTM standards. The purpose of the hexane soak is to leach any absorbed fatty acids from the explanted materials. 2015 Spiegelberg Dep. at 49:15-25; 52:22-53:13. While Plaintiffs contend that Dr. Spiegelberg could not cite any peer-reviewed literature that polypropylene mesh absorbs fatty acids, this is simply a misstatement of his testimony. Dr. Spiegelberg did indeed identify literature and authors who have investigated the absorption of fatty acids into medical plastics, including Clave, who studied polypropylene mesh explants.[5] *See, id.* at 56:7-57:12 (identifying Clave); 79:10-80:25 (identifying work of University of Turin researchers, Harry McCallum at Vernon Loke, University in California as examples). Once again, to the extent Plaintiffs take issue with Dr. Spiegelberg's reading of the Clave article, or wish to challenge the fact that polypropylene can absorb fatty acids, it is a matter for cross examination. And, again, Plaintiffs criticize the possible chemical reactions between the hexane, the tissue, and the additives in the polypropylene without offering any support that these criticisms are valid. While Plaintiffs continually portray a "destruction" of "plaintiffs' evidence of oxidation," their own experts had access to the same specimen samples and could have completed testing to affirm their theory of oxidation.

2. Dr. Spiegelberg's Analytical Techniques are Widely-Accepted and Industry Standard.

Plaintiffs also criticize Dr. Spiegelberg's "instrumental analyses," despite the use of the same techniques by their experts. Dr. Spiegelberg noted the compliance of the explanted mesh

[5] Clave, et al., *Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants.* Int Urogynecol J (2010) 21:261-270. Attached as Exhibit D.

samples after removing the adherent biologic tissue and compared it to mesh that had never been implanted. Dr. Spiegelberg does not extrapolate this data to mechanical performance and Plaintiffs' critique that no "standardized testing" was done is immaterial. In his Supplemental Reports, Dr. Spiegelberg simply notes, based on his handling of pristine and explanted mesh, that the explanted mesh is as compliant after tissue is removed. This is relevant to Plaintiffs' claims that mesh becomes "stiff" or "hard" inside the body. Moreover, it is helpful to the jury, who has never handled pristine or explanted mesh samples, especially those from which adherent biological tissue has been removed.

Plaintiffs next contend that Dr. Spiegelberg was aware of limitations with FTIR, SEM, and EDS, but "did not acknowledge them in his case-specific opinions." This is simply untrue. Plaintiffs' first contention is that (very) low concentrations of oxidation would not have been picked up by FTIR. Dr. Spiegelberg would admit that if carbonyls were present below the level of detection, that FTIR would not demonstrate a carbonyl peak, and notes that his FTIR suggests no "measurable oxidation." Supp. Report at p. 2. Plaintiffs also misstate Dr. Spiegelberg's testimony regarding baseline correction – while baseline correction can be done, Dr. Spiegelberg repeatedly told Plaintiffs that he does not like to do baseline corrections. 2015 Spiegelberg Dep. at 91:10-92:2; 105:19-106:11. Dr. Spiegelberg (and his lab at Cambridge Polymer Group) usually does not use baseline correction because it is an arbitrary, not reproducible method and can create and remove peaks from the FTIR. Moreover, Plaintiffs do not offer any evidence that a baseline correction would have changed the significance of Dr. Spiegelberg's findings. Instead, they allude to some "significant insight" without providing facts or evidence to support these "insights." Mot. to Exclude at p. 9.

Plaintiffs then continue to outline a cross-examination strategy for Dr. Spiegelberg by addressing the EDS results and Dr. Spiegelberg's final conclusions regarding oxidation in the mesh explant samples. Whether oxygen present in EDS is indicative of oxidation is a prime topic for trial examination, as is Dr. Spiegelberg's conclusions that a certain mesh explant had not oxidized. Regarding the absorption of fatty acids, Dr. Spiegelberg's testimony is again misconstrued. While Dr. Spiegelberg did use "an abundance of hexane," the purpose of that was to prevent equilibrium. 2015 Spiegelberg Dep. at 55:12-56:6. Dr. Spiegelberg also stated repeatedly that the use of the hexane soak is to remove as much fatty acids as possible, but that all the absorbed material cannot always be removed. *Id.* at 52:22-53:13.

F. Dr. Spiegelberg's General Causation Opinions Should Not be Limited.

In a final effort to limit Dr. Spiegelberg's opinions, Plaintiffs try to limit Dr. Spiegelberg's "general causation" opinions based on his "admissions regarding the usefulness of FTIR and EDS." Mtn. to Exclude at 11. This argument is based on Plaintiffs' arguments outlined above regarding Dr. Spiegelberg's explant testing. Here, Plaintiffs admit that the limitations of scientific techniques are normally grounds for cross-examination. This was recognized by this Court in previously denying this same motion. *See Frankum*, 2015 WL 1976952, at *37. Yet, Plaintiffs confusingly argue that Dr. Spiegelberg should not be allowed to offer opinions regarding the lack of scientific evidence to support the theory of *in vivo* oxidative degradation. Plaintiffs somehow conclude that this opinion is "based on FTIR and EDS results, alone." Foremost, Dr. Spiegelberg does not base his opinions on FTIR and EDS results alone. Rather, he bases his opinions on his experience and knowledge working with polymers and biomaterials, his review of the scientific and medical literature, and his own testing and analysis of polypropylene inside and outside of litigation. Additionally, it is unclear what "admissions" Dr. Spiegelberg made regarding the "data

that can be reasonably extrapolated using FTIR and EDS techniques." Dr. Spiegelberg, as would any other scientist, recognizes that scientific techniques have limitations to take into account. But the techniques he uses here, including FTIR and EDS, are widely accepted and used in the area of polymer analysis, including by Plaintiffs' expert witnesses, Dr. Russell Dunn and Dr. Jimmy Mays. 2015 Spiegelberg Dep. at 31:8-14. Plaintiffs' argument is unclear and inappropriate in the context of a *Daubert* motion and Plaintiffs' Motion must be denied.

CONCLUSION

For all of the foregoing reasons, the Court should deny Plaintiffs' Motion to Exclude the Opinions and Testimony of Dr. Stephen Spiegelberg in its entirety. The opinions Dr. Spiegelberg offers in these cases are in harmony with the Court's prior Orders; are within the scope of his expertise; and are the product of a reliable scientific methodology.

Dated: February 1, 2018

Respectfully Submitted

By: /s/ *Eric M. Anielak*

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CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this matter.

/s/ Eric M. Anielak
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